chlorpyrifos exposures and damage to children's brains, and also found lung damage in 11-year olds and tremors that could impair their ability to draw and write.[43] The comments continued to urge EPA to develop an endpoint or restore the traditional safety factors to protect children from this harm, and conducted calculations based on the 2014 risk assessment to add such protection, which showed that exposures are unsafe from food alone, all drinking water, and from drift at distances greater than those covered by the spray drift buffers put in place in 2012. The comments cited evidence that chlorpyrifos travels further, including a Washington incident when workers were sickened by chlorpyrifos being applied about a mile from their worksite.[44]

## VII. EPA FOUND SERIOUS HARM, PARTICULARLY TO CHILDREN, AT LOWER EXPOSURES IN ITS MOST RECENT ASSESSMENTS

To protect against damage to children's brains from low-level exposures and to ensure that its regulatory actions are based on the most sensitive endpoint, consistent with longstanding EPA policy, EPA sought to identify a regulatory endpoint from the Columbia study that correlated chlorpyrifos exposures with serious harm to children's brains.[45] In 2016, EPA used measurements of chlorpyrifos in cord blood from the Columbia study to derive a more protective endpoint that would protect against adverse brain impacts, heeding a recommendation of the 2012 SAP. EPA submitted its analysis to the SAP for review. Even though the SAP did not support EPA's particular methodology for deriving such an endpoint, the SAP concurred with EPA's conclusion in the 2014 risk assessment that the 10% cholinesterase inhibition endpoint is not protective because damage to children's brains occurred at lower doses and EPA should take steps to protect against this harm. 2016 SAP at 18, 52-53.[46]

In November 2016, EPA released its 2016 Chlorpyrifos Revised Human Health Risk Assessment ("2016 RHHRA").[47] EPA derived a regulatory endpoint based on neurodevelopmental effects because the Agency had determined that neurodevelopmental harm to fetuses occurred when pregnant mothers were exposed to far lower doses of chlorpyrifos than what produces 10% cholinesterase inhibition. 2016 RHHRA at 13. EPA considered all lines of

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[43] Earthjustice, et al Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 5, 2016) at 7 (EPA-HQ-OPP-2015-0653-0390).

[44] *Id.* at 21 (citing Washington State Department of Health Comments (May 8, 2015) (EPA-HQ-OPP-2008-0850-0842)).

[45] Also, as EPA continued to review the scientific evidence correlating low-level exposures to chlorpyrifos and other organophosphates with damage to children's brains, it reiterated and expanded its findings substantiating this harm to all organophosphates, given that they share a common mechanism of toxicity, and extensive scientific evidence correlates organophosphates with adverse neurodevelopmental effects. *See* Literature Review on Neurodevelopment Effects and FQPA Safety Factor Determination for the Organophosphate Pesticides (Sept. 2015), *available at* https://www.regulations.gov/%23!documentDetail;D=EPA-HQ-OPP-2008-0440-0039.

[46] FIFRA Scientific Advisory Panel Minutes No. 2016-01, A Set of Scientific Issues Being Considered by the EPA Regarding Chlorpyrifos:Analysis of Biomonitoring Data) (Apr. 2016), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0062-0140.

[47] Chlorpyrifos Revised Human Health Risk Assessment (Nov. 3, 2016) (EPA-HQ-OPP-2015-0653-0454).

evidence, including human epidemiological and animal toxicological studies in making its determination to change its endpoint. 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (agreeing with Scientific Advisory Panel that existing point of departure based on 10% cholinesterase inhibition is "not sufficiently health protective"). EPA also retained the FQPA 10X safety factor to account for uncertainty in using a lowest-observable adverse effect level in the absence of a no-observable adverse effect level. 2016 RHHRA at 22.[48]

In establishing an updated regulatory endpoint, EPA used the physiologically based pharmacokinetic ("PBPK") model developed by Dow AgroSciences as a tool to analyze exposure estimates. EPA followed the recommendation of the 2016 Scientific Advisory Panel and used the PBPK model to predict a time-weighted average blood concentration for women in the Columbia cohort. 2016 RHHRA at 16-17. EPA applied the average blood concentration to females, infants, and young children, which was supported by data from animal studies showing that both the pre- and post-natal periods are windows of susceptibility.[49]

Using this more appropriate endpoint, EPA found that chlorpyrifos presents unacceptable safety risks through exposures from food, drinking water, spray drift, and occupational activities. Food-only exposures for chlorpyrifos were found to be unsafe for all population subgroups analyzed, with young children having the highest risks of concern. 2016 RHHRA at 23. While the adult subgroup had an alarming risk estimate at 62 times the safe level of exposure, the risk estimate for children ages 1-2 was more than double that of adults at 140 times safe levels. *Id.* Additionally, EPA's revised assessment did not result in any changes to its finding that "the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures." 81 Fed. Reg. at 81,050. Regarding spray drift, EPA found unsafe levels of chlorpyrifos from the field's edge to distances of more than 300 feet from where the pesticide is sprayed and unsafe levels in the ambient air recorded in air monitoring performed in agricultural communities in California and Washington. 2016 RHHRA at 31. EPA also found unacceptable risks to all farmworkers who mix and apply chlorpyrifos, even with maximum levels of personal protective equipment or engineering controls. 2016 RHHRA at 36-37. Moreover, even though current labels allow workers to re-enter the fields within 1-5 days after pesticide spraying to weed, irrigate, and pick crops, EPA found that, on average, re-entry intervals of at least 18 days were needed to protect workers from risks of concern. *Id.* at 38.

After releasing the 2016 RHHRA, EPA reopened the comment period for its proposal to revoke chlorpyrifos food tolerances, noting that:

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[48] EPA's longstanding risk assessment methods apply an additional uncertainty or safety factor when the scientific studies do not identify a no-observable adverse effect level. EPA then uses and extrapolates from the lowest-observable adverse effects level, and adds a safety factor to guard against exposing people to the observed adverse effects. EPA Office of Pesticide Programs, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment* at 9 (Feb. 28, 2002) (https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf).

[49] EPA reviewed animal studies and found at in its 2014 Revised Human Health Risk Assessment for Chlorpyrifos that, "There is a considerable and growing body of literature on the effects of chlorpyrifos on the developing brain of laboratory animals (rats and mice) indicating that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood. These data provide support for the susceptibility of the developing mammalian brain to chlorpyrifos exposure." 2014 RHHRA at 25-26.

> EPA's revised analyses do not result in a change to the EPA's proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP. The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the ''reasonable certainty of no harm'' safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures. Accordingly, based on current labeled uses, the agency's analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard. EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe. EPA has not identified a set of currently registered uses that meets the FFDCA safety standard because it is likely only a limited number of food uses alone, and in combination with predicted drinking water exposures, would meet the standard. Further, EPA has not received any proposals for mitigation that registrants may be willing to undertake that would allow the EPA to retain any of the tolerances subject to this rulemaking.

81 Fed. Reg. at 81,050.

This was the state of the record as the March 31, 2017 court-ordered deadline approached. EPA had found chlorpyrifos unsafe due to drinking water contamination in 2014, leading to the 2015 proposal to revoke all tolerances. No mitigation or further analysis lessened the risks. To the contrary, as EPA conducted further assessment to determine what action is necessary to guard against damage to children's developing brains, it found unsafe exposures every way people come into contact with chlorpyrifos whether in food, in drinking water, or in the air. And young children are most at risk. The fate of chlorpyrifos had been all but sealed.

## VIII. THE ORDER DENYING THE 2007 PETITION

Instead of finalizing the proposed revocation order based on its findings that chlorpyrifos is unsafe, on March 29, 2017, the new EPA Administrator, Scott Pruitt, issued an order on March 29, 2017, entitled "Chlorpyrifos: Order Denying PANNA and NRDC Petition to Revoke Tolerances" ("Pruitt Order"), 82 Fed. Reg. 16,581, 16,583 (Apr. 5, 2017). The Pruitt Order finalized the interim responses EPA had previously provided addressing spray drift, volatilization, endocrine disruption screening, cancer risks, export hazards, and other issues. The Pruitt Order reiterated the interim responses, even where subsequent EPA action had reversed or severely undermined the rationale for the earlier partial response based on further analysis or new scientific evidence. For example, EPA defended dispensing with the FQPA 10X safety factor for chlorpyrifos, even though it decided in 2014 that the FQPA safety factor had to be retained in full. *Id.* at 16,588-89. EPA also repeated its earlier justification for not considering genetic vulnerability to chlorpyrifos, even though the Dow model used in EPA's 2014 and 2016 risk assessments incorporated such genetic variability into its metrics. *Id.* at 16,585-86. And EPA adhered to its incomplete assessment and mitigation for spray drift and volatilization,

without ever acknowledging, let alone addressing, the public comments criticizing EPA's approach as legally and scientifically flawed.

With the exception of the FIFRA export claim not at issue here, EPA had indicated that it would not make its interim, partial responses final, unless PAN and NRDC requested that it do so. *See id.* at 16,583, 16,585. PAN and NRDC did not ask EPA to make the partial responses final because the heart of the 2007 Petition — neurodevelopmental harm to children from chlorpyrifos at low doses — remains unresolved. Resolution of that issue in a manner that protects children would lead to revocation of chlorpyrifos tolerances and eliminate the need for objections and further proceedings. Moreover, EPA had not addressed the comments submitted by PAN, NRDC, and others, criticizing the spray drift mitigation and interim volatilization determination because they were based on poisoning risks and not damage to children's brains at lower doses. Nor had EPA yet addressed comments making the case that EPA: (1) had illegally ignored direct drift and inhalation exposures in its spray drift assessment and mitigation; and (2) had backtracked from its volatilization assessment documenting unsafe exposures far from the application site based on two scientifically flawed Dow studies.

PAN and NRDC believed that EPA would follow the law and science, and revoke all chlorpyrifos tolerances once it developed a regulatory endpoint and risk assessments that would protect children from neurodevelopmental harm, and once it addressed the public comments revealing serious flaws in its approach to spray drift and volatilization. While EPA did revise its human health risk assessment in 2016 based on a regulatory endpoint designed to prevent low-level exposures associated with brain damage to children, the Pruitt Order made no final decisions and took no final action based on that assessment or any other approach that would protect children's brains. Nor did the Pruitt Order address the public comments revealing flaws that made its treatment of spray drift and volatilization to date under-protective, particularly of children.

As to the one issue EPA had not previously resolved — neurodevelopmental harm from chlorpyrifos — the Pruitt Order made no substantive determination. Despite EPA's repeated findings that chlorpyrifos is unsafe, the Pruitt Order did not finalize the tolerance revocation rule. Instead, the Pruitt Order postponed such action based on the Administrator's preference to engage in further study of the harm to children's brains from chlorpyrifos before finalizing the October 2015 proposed revocation rule or taking an alternative regulatory path. *Id.* at 16,590. Without any elaboration, the Pruitt Order asserted vaguely that comments received in response to the October 2015 proposed rule and its November 2016 risk assessment suggest some stakeholders believe uncertainty persists about the use of epidemiological data in risk assessments. *Id.*

EPA framed its delay in deciding whether to revoke chlorpyrifos food tolerances as a reprioritization of the chlorpyrifos registration review schedule developed by earlier administrations. *Id.* EPA asserts that, while the Ninth Circuit's order compelled a response to the 2007 Petition, the court "cannot compel EPA to complete the registration review of chlorpyrifos in advance of the October 1, 2022 deadline" for registration review of all older pesticides. *Id.*

Acknowledging that it is not legally a relevant factor, the Pruitt Order nonetheless stated: "it is important to note that for many decades chlorpyrifos has been and remains one of the most

widely used pesticides in the United States" and that a decision to remove the pesticide from the market would be a "significant policy choice." *Id.* Citing the significance of the decision and uncertainty regarding the correlation between chlorpyrifos and adverse neurodevelopmental effects, the Pruitt Order expressed the Administrator's preference to engage in further study before finalizing any regulatory action. *Id.*

Within a week of EPA's Pruitt Order, PAN and NRDC filed a motion with the Ninth Circuit seeking further mandamus relief because EPA had essentially given itself an open-ended extension of time to make chlorpyrifos tolerance decisions, rather than take action on the 2007 Petition and EPA's findings that chlorpyrifos is unsafe. Specifically, PAN and NRDC asked the Ninth Circuit to give EPA a 30-day deadline to take final regulatory action by either: (1) revoking chlorpyrifos tolerances based on its findings that chlorpyrifos is unsafe; or (2) denying the 2007 Petition if EPA could find chlorpyrifos safe. The motion also asked the court to establish a deadline for EPA to resolve any objections filed contesting its final tolerance action. The motion was fully briefed on May 5, 2017. If the Ninth Circuit fully grants the motion, it will moot these objections.

## OBJECTIONS

The EPA Administrator's decision to leave chlorpyrifos tolerances in place cannot stand for two reasons. First, the decision violates the law, which allows the Administrator to leave tolerances in place only if he finds the pesticide safe. EPA has repeatedly found chlorpyrifos unsafe. The Administrator therefore lacks the legal authority to retain tolerances for this harmful pesticide. Second, the Administrator's rationale for putting off regulatory action on chlorpyrifos is indefensible under both the law, given EPA's findings chlorpyrifos is unsafe, which flow from the solid and extensive scientific evidence before the agency. The Pruitt Order should be reversed, and EPA should issue a final revocation rule on an expeditious basis. It should take EPA no longer than 60 days to rule on these objections because they present purely legal issues, and EPA has an obligation to resolve objections "as soon as practicable". *See* 21 U.S.C. § 346a(g)(2)(c) (EPA Administrator must issue an order on objections "as soon as practicable").

### I. EPA'S DENIAL OF THE 2007 PETITION IS ILLEGAL BECAUSE EPA CANNOT MAINTAIN TOLERANCES IN THE FACE OF ITS FINDINGS THAT CHLORPYRIFOS IS UNSAFE

EPA's decision to leave chlorpyrifos tolerances in place violates the law and exceeds the Administrator's legal authority. Under the FFDCA, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food *only if* the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i) (emphasis added). "Safe" means the Administrator has determined that there is a reasonable certainty of no harm from aggregate exposures to the pesticide chemical residue. *Id.* § 346a(b)(2)(A)(ii). The law spells out the consequences of an inability to make the required safety finding in a way that leaves no discretion: "The Administrator *shall* modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* § 346a(b)(2)(A)(i) (emphasis added). Because EPA has repeatedly found chlorpyrifos to be unsafe, the Administrator must revoke all food tolerances for chlorpyrifos.

EPA first found unsafe drinking water exposures and proposed to revoke all chlorpyrifos tolerances on this basis, which is addressed in A below. When EPA took steps to protect children from neurodevelopmental harm, it found chlorpyrifos unsafe every way people are exposed to it, which is addressed in B below.

### A. EPA Found Unsafe Drinking Water Contamination from Chlorpyrifos Using Poisoning Risks as the Regulatory Endpoint

After years of study and several rounds of review by its Scientific Advisory Panel, EPA has made an unbroken series of findings that chlorpyrifos harms children's brains at lower exposures than those used by EPA in its previous risk assessments and regulatory decision. EPA's analysis of the scientific evidence and several SAP reviews culminated in the 2014 risk assessment, which found that chlorpyrifos causes harm to children's brains from prenatal exposures and that this harm occurs at exposures far lower than EPA's regulatory endpoint, 10% red-blood cell cholinesterase inhibition. This finding, coupled with uncertainties about the precise low-level exposures that damage children's developing brains, led EPA to retain the FQPA tenfold margin of safety to protect children from neurodevelopmental harm. The 2014 risk assessment documented drinking water contamination from chlorpyrifos that exposed children to unsafe levels of the pesticide. 2014 RHHRA at 48-49, 95-96.

In October 2015, EPA proposed to revoke all tolerances because it could not "determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe." 80 Fed. Reg. 69,080, 69,081 (Nov. 6, 2015). EPA explained:

> Section 408(d) of the FFDCA, 21 U.S.C. 346a(d), authorizes EPA to revoke tolerances in response to administrative petitions submitted by any person. Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances in response to a Petition from PANNA and the Natural Resources Defense Council (NRDC) to revoke all chlorpyrifos tolerances . . ..This proposal also implements the agency findings made during the registration review process required by section 3(g) of FIFRA (7 U.S.C. 136(a)(g)) which EPA is conducting in parallel with its petition response.

*Id.* EPA's proposal to revoke chlorpyrifos tolerances is replete with findings that chlorpyrifos is unsafe:

> EPA cannot determine that current dietary exposures to chlorpyrifos are safe within the meaning of FFDCA section 408(b)(2)(A). [*Id.* at 69,106.]
>
> EPA cannot find that any current tolerances are safe and is therefore proposing to revoke all chlorpyrifos tolerances. [*Id.*]
>
> [F]ood exposures, when aggregated with residential exposures and potentially more significant drinking water exposures do present a significant risk concern and support revocation of all chlorpyrifos tolerances. [*Id.* at 69,097.]

> [W]e cannot make a safety finding based on drinking water exposure. [*Id.* at 69,106.]

*See also* Declaration of Richard P. Keigwin, Jr., EPA Office of Pesticide Programs, ¶ 5, in *In re PANNA*, No. 14-72794, Dkt. No. 25-2 (9th Cir. Oct. 29, 2015) (proposed rule is "based on EPA's conclusion that it could not make the 'reasonable certainty of harm' finding").

### B. EPA Found All Exposures to Chlorpyrifos to be Unsafe When it Sought to Protect Against Damage to Children's Developing Brains

EPA's findings that chlorpyrifos is unsafe flow from the 2014 risk assessment, which uses 10% red blood cell cholinesterase inhibition as the regulatory endpoint. That risk assessment, however, contained a pivotal, and troubling, finding: the damage to children's brains in the mother-child cohort studies occurred from exposures that were too low to produce cholinesterase inhibition. 2014 RHHRA at 47, 49. In its proposal to revoke chlorpyrifos tolerances, EPA indicated it would heed the SAP's advice and try to reconstruct the exposures correlated with adverse brain impacts in the Columbia study or find some other method to protect against this type of harm. This attempt to identify exposures linked to damage to the developing brain is consistent with EPA's policy to ensure that its risk assessments are designed to identify and protect the most sensitive endpoint. While the 2016 SAP did not agree with EPA's first effort to reconstruct the exposure levels based on cord blood samples from the Columbia study, it agreed with EPA that the harmful brain impacts occurred at exposures far below EPA's regulatory endpoint based on cholinesterase inhibition and that EPA should be more protective to guard against such impacts. 2016 SAP at 18, 52-53.

EPA's second effort, released in November 2016, was based in large part on Dow's PBPK model and showed that people will be at risk of harm from virtually every use and every way that people are exposed to chlorpyrifos, with children, and particularly 1 to 2- year olds, most at risk. 2016 RHHRA at 23. With the lower endpoint, the 2016 risk assessment revealed even higher and more pervasive risks from chlorpyrifos:

> All food exposures exceed safe levels, with the most exposed population - children 1-2 years of age - exposed to 140 times what EPA deems to be safe.
>
> Use of chlorpyrifos contaminates drinking water.
>
> Drift of pesticides from the fields expose children to unsafe levels of chlorpyrifos within 300 or more feet of the fields where the pesticide is sprayed. Children could be exposed to harmful drift at schools, day cares, in their homes, and at playgrounds.
>
> For children between 1 to 2- years old, all 11 acute ambient air concentrations assessed resulted in risks of concern. For adults, all but one of the 11 steady state ambient air concentrations assessed resulted in risks of concern.
>
> All workers who mix and apply chlorpyrifos pesticides are exposed to levels greater than what EPA deems to be safe.

> Field workers are currently allowed to re-enter fields within 1-5 days after pesticide spraying, but unsafe exposures continue on average for 18 days after applications.

*Id.* at 23-24, 30-33.

Not surprisingly, EPA found based on the 2016 risk assessment:

> The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures. Accordingly, based on current labeled uses, the agency's analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard. EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe. EPA has not identified a set of currently registered uses that meets the FFDCA safety standard . . . .Further, EPA has not received any proposals for mitigation that registrants may be willing to undertake that would allow the EPA to retain any of the tolerances subject to this rulemaking.

81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016) (citing 2016 RHHRA).

### C. EPA's Findings that Chlorpyrifos is Unsafe Compel the Administrator to Revoke All Chlorpyrifos Food Tolerances

In the face of these findings, which build upon the 2014 risk assessment and 2015 tolerance revocation proposal, the EPA Administrator has a legal obligation to revoke all chlorpyrifos tolerances. This is the only legally defensible course of action under the law, which allows the Administrator to leave a tolerance in place "only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). Beginning in 2014, EPA has repeatedly stated that it cannot find chlorpyrifos safe and it has since found chlorpyrifos unsafe every way that people are exposed to it. In the face of these findings, the law is clear: "the Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.*

This mandatory obligation is reinforced by the FFDCA's provisions laying out the "actions" the Administrator is authorized and directed to take on a petition to revoke tolerances. The FFDCA provides that the Administrator "shall" take one of three permissible actions:

> (i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue …(which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e) of this section and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

*Id.* § 346a(d)(4)(A).

These actions are stated in the alternative, meaning they are mutually exclusive paths the Administrator may take on a petition or specific part of a petition. The second option starts with a proposed regulation and proceeds to a final regulation after notice and public comment. Here, in contrast, EPA proposed to revoke chlorpyrifos tolerances, but did not finalize that regulation. He left the proposed revocation rule intact, awaiting further final action. Administrator Pruitt then issued an order purporting to deny the 2007 Petition, but without withdrawing the proposed regulation because he did not resolve the merits of the 2007 Petition. The FFDCA does not allow the Administrator to take these two mutually exclusive actions on the same issue concurrently. For this reason as well, the Administrator acted in blatant violation of the law by denying the 2007 Petition and leaving chlorpyrifos tolerances in place.

## II. EPA'S RATIONALE FOR LEAVING CHLORPYRIFOS TOLERANCES IN PLACE IS LEGALLY AND SCIENTIFICALLY INDEFENSIBLE

The Pruitt Order offers several reasons for delaying action on chlorpyrifos tolerances for many years, possibly until October 1, 2022. None can legally justify defying the clear legal mandate to revoke tolerances because EPA cannot find chlorpyrifos safe.

### A. EPA Cannot Rely on Its 2006 Safety Finding When It Has Since Determined Based on Mounting Scientific Evidence that Chlorpyrifos Damages Children's Brains and is Unsafe

The 2007 Petition sought to compel EPA to address and act on scientific evidence and routes of exposure disregarded in its old risk assessments used in re-registering chlorpyrifos in 2001 and 2006. Oddly, the Pruitt Order defends the 2006 cumulative risk assessment based on the science then available as if time stood still. *See, e.g.,*82 Fed. Reg. at 16,589 ("the Agency is confident that its assessment for chlorpyrifos in 2006 was reasonably based on the best available science *at the time of the assessment*") (emphasis added). To state the obvious, it is no longer 2006. EPA must address the extensive and ever-growing evidence of serious brain damage to children from chlorpyrifos, developed over the past 11 years. *See* 21 U.S.C. § 346a(d)(4) (EPA must assess available information); *id.* § 346a(b)(2)(C)-(D) (EPA must consider available information concerning such factors as toxicity, population sensitivities, and children's exposures).

The Pruitt Order also depicts much of the 2007 Petition as a challenge to the 2006 re-registration determination when the heart of the Petition sought action on issues EPA had sidestepped in 2006, namely drift, volatilization, and damage to the developing brain. *See* 82 Fed. Reg. at 16,590. At one point, the Pruitt Order defends eliminating the FQPA 10X safety factor, even though EPA decided in 2014 that it must retain that safety factor due to gaps in information needed to protect infants and children. *Id.* at 16,588. The Pruitt Order asserts that PAN and NRDC failed to show that using a FQPA 10X safety factor would show chlorpyrifos is unsafe. *Id.* That statement is mind-boggling in light of EPA's findings in its 2014 and 2016 risk

assessments (that retain a FQPA 10X safety factor) that chlorpyrifos is unsafe, which compels revocation of all chlorpyrifos tolerances.

EPA cannot continue to rely on its 2006 safety finding in light of the Agency's and multiple SAP's subsequent findings that chlorpyrifos fails to meet the FQPA safety standard based on an extensive body of peer-reviewed toxicological and epidemiological studies correlating neurodevelopmental harm to fetuses and children with chlorpyrifos exposure. As the Ninth Circuit Court of Appeals noted, EPA "has backtracked significantly from" its 2006 pronouncement of safety when it found chlorpyrifos unsafe in its 2014 risk assessment and determined its tolerances needed to be revoked. *In re PANNA v. EPA*, 798 F.3d at 814. The FQPA gives EPA only two options: the Agency must find that chlorpyrifos is safe based on the evidence currently before it in order to retain chlorpyrifos tolerances, which it cannot do, or it must revoke tolerances based on its findings that chlorpyrifos is unsafe. Hiding behind stale 2006 findings that have since been reversed based on numerous, definitive studies and EPA and SAP findings is not an option.

### B. Scientific Uncertainty is Not a Legally Permissible Reason to Leave Chlorpyrifos Tolerances in Place

The primary justification offered in the Pruitt Order for failing to revoke chlorpyrifos tolerances in the face of its prior findings that chlorpyrifos exposures are unsafe is that the Administrator prefers to engage in further study. 82 Fed. Reg. at 16,590 ("EPA's preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional peer review of EPA's risk assessment prior to finalizing any regulatory action in the course of registration review."). The Pruitt Order states that:

> EPA has concluded that, despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution of those issues.

82 Fed. Reg. at 16,583; *see also id.* at 16,590 ("the science on this question is not resolved and would likely benefit from further inquiry.").

#### 1. The Science Underlying EPA's Findings that Chlorpyrifos is Unsafe is Well-Settled

In putting off action on the 2007 Petition and its proposal to revoke chlorpyrifos tolerances, the Pruitt Order alludes generally to scientific uncertainties, ignoring how much progress has been made in assessing the mounting scientific evidence of neurodevelopmental harm from chlorpyrifos exposures and the weight of the scientific evidence. EPA and the SAP have consistently found that chlorpyrifos causes damage to children's developing brains and that this damage has resulted from exposures that are far lower than EPA's regulatory endpoint. The

chlorpyrifos tolerances currently in place do not protect against these adverse brain impacts. On this point, assertions of scientific uncertainty ring hollow given the overwhelming scientific evidence and the unbroken EPA and SAP findings.

When EPA convened its SAP in 2008 to review post-re-registration science, the SAP found that prenatal and early postnatal chlorpyrifos exposures can produce long-lasting cognitive and motor impairments. 2008 SAP Report at 11-12. The SAP also found that the exposures associated with this serious harm were below EPA's regulatory endpoint. *Id.* at 43-44. In 2012, the SAP again found, based on more extensive scientific review, that chlorpyrifos is associated with abnormal reflexes, mental deficiencies, and attention and behavioral problems from exposures lower than those associated with cholinesterase inhibition, EPA's regulatory endpoint. 2012 SAP at 17, 19. Even the 2016 SAP, which disagreed with EPA's first attempt to quantify exposures correlated with such brain damage, agreed that chlorpyrifos harms children's brains at exposures far below EPA's regulatory endpoint and that EPA needs to be more protective than its 2014 risk assessment. 2016 SAP 18, 52-53.

EPA's risk assessments have, since 2011, similarly found correlations between low-level chlorpyrifos exposures and long-lasting harm to children's brains. The 2011 PHHRA found that chlorpyrifos played a role in causing such neurodevelopmental harm. 2011 PHHRA at 8. The 2014 RHHRA made even stronger findings from multiple lines of evidence that chlorpyrifos results in neurodevelopmental harms to children, such as reduced IQ, delays in mental development, and attention disorders, and that the exposures associated with these brain impairments were too low to produce cholinesterase inhibition. 2014 RHHRA at 41-43, 46.

There may be scientific uncertainty on other issues, but not as to these uncontestable findings. And these findings alone revealed in the 2014 RHHRA that chlorpyrifos is unsafe due to drinking water contamination. *Id.* at 48-49, 95-96.

Scientific uncertainty remains as to the mode of action by which chlorpyrifos damages children's brains and the exact dose at which such effects occur. EPA does not need to know the precise mode of action to know that harm is occurring and that the statutory safety standard is being violated. *See id.* at 48. Nor does EPA need to know the precise dose at which neurodevelopmental harm occurs, given that such harm is occurring at exposures so far below the regulatory endpoint supporting the current chlorpyrifos tolerances that EPA cannot identify a safe exposure level. As explained below, Congress has prescribed how EPA must deal with such uncertainties in protecting the safety of our food supply and preventing harm to children.

2. Congress Directed EPA to Revoke Tolerances if Scientific Uncertainty Precludes Finding the Pesticide Safe.

Congress has established a statutory standard that precludes delaying protection, particularly to children, due to scientific uncertainty when there is evidence of harm. This direction manifests itself in three ways.

First, EPA can "leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i). An affirmative finding of safety is a prerequisite to establishing or retaining a tolerance. And if EPA determines a pesticide is not safe, "[t]he Administrator *shall* modify or revoke a tolerance."

*Id.* (emphasis added). EPA acknowledged the statutory mandates in its proposed revocation rule, stating: "It is important to stress, however, that because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe." 80 Fed Reg. 69,080 (Nov. 6, 2015). Explicitly requiring a safety finding to retain a tolerance reinforces longstanding precedent that places the burden of proof on EPA and industry registrants seeking to retain food tolerances to prove safety. *See Envtl. Def. Fund, Inc. v. U.S. Dep't of Health, Ed. & Welfare*, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970) (following petition for revocation, burden of establishing the safety of any tolerance is on those seeking to permit a residue).[50] EPA is mistaken in asserting in the Pruitt Order that petitioners bear the burden of proving that chlorpyrifos is unsafe. 82 Fed. Reg. at 16,587-88.[51] When EPA adhered to the regulatory safety standard and burdens, it proposed to revoke all chlorpyrifos tolerances.

Second, "safe" means that EPA "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue...." 21 U.S.C. § 346a(b)(2)(A)(ii). Not only must EPA make a safety finding to retain a tolerance, it must find a reasonable certainty of no harm. The fact that chlorpyrifos is associated with serious brain damage at low doses makes it impossible for EPA to find a reasonable certainty of no harm from exposures allowed under the current tolerances.

Third, other FQPA provisions further specify how EPA must deal with scientific uncertainty. The FQPA directs EPA to act on the basis of available information on the special susceptibility of infants and children, including neurological differences between adults and infants and children, and EPA must apply an additional tenfold margin of safety to account for gaps in data or evidence of pre- or post-natal toxicity to children. 21 U.S.C. § 346a(b)(2)(C).

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[50] The court's reasoning (*id.*) applies with even greater force to the FFDCA standard, as amended by the FQPA.

> Section 408 of the FDCA authorizes the Secretary of HEW to establish tolerances for pesticide residues on or in raw agricultural commodities 'to the extent necessary to protect the public health.' The section also authorizes the setting of a zero tolerance (no residue) level 'if the scientific data before the Secretary does not justify the establishment of a greater tolerance.' We need not pause to plumb the obvious ambiguities in this language since both Senate and House Committee Reports make the intended meaning of this section indisputably clear:
>
> 'Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.'

[51] The Pruitt Order states that EPA proposed to revoke all chlorpyrifos tolerances based in part on uncertainty surrounding the correlation between chlorpyrifos exposures and longlasting neurodevelopmental harm. 82 Fed. Reg. at 16,583, 16,590. However, EPA proposed to revoke chlorpyrifos tolerances because it could not find chlorpyrifos safe. To the extent the Pruitt Order is referring to the requirement that EPA be able to find safety in order to retain tolerances, that is what Congress has mandated.

Congress specifically directed EPA to act to protect children where scientific evidence shows they are at risk of harm and it will take time to fill in gaps in the data.

In 2014, EPA retained the FQPA tenfold safety factor because of gaps in scientific information on the mode of action and exposure levels by which chlorpyrifos causes damage to children's brains. It recognized, however, that the 2014 risk assessment was under-protective because it continued to use cholinesterase inhibition as the regulatory endpoint, and that brain damage to children has resulted from lower exposure levels. In the face of this evidence, EPA also recognized that it needed to lower its regulatory endpoint or have additional safety factors to protect children's brains, and the 2016 SAP concurred. 2016 RHHRA at 13-14; 2016 SAP at 18-19.

The uncertainties go to the precise exposure level to use or additional safety factors to include in establishing a brain-protective regulatory endpoint. That uncertainty offers no reason to retain tolerances, however. In 2014, even using a poisoning regulatory endpoint that is not protective of children's brains, EPA found chlorpyrifos unsafe due to drinking water contamination. When it developed a regulatory endpoint that would protect children's brains, it found chlorpyrifos unsafe every way people are exposed to it with young children exposed to 140 times safe levels in food.[52] More study will simply confirm how hazardous and devastating this pesticide can be. Congress decided not to expose children to such risks by precluding EPA from maintaining tolerances when it cannot find a reasonable certainty of no harm from the pesticide.

3. The Pruitt Order Fails to Address Significant Concerns Raised in Comments that EPA's 2014 Risk Assessment and Proposed Revocation Fail to Protect Children.

The Pruitt Order indicates that EPA decided that the science regarding neurodevelopmental harm from chlorpyrifos remains unresolved and warrants further study before final regulatory action "[f]ollowing a review of comments" on the proposed revocation and 2016 risk assessment. 82 Fed. Reg. at 16,583. While it is typical for EPA to prepare a response to comments as part of a rulemaking, no response to comments document is in the administrative records for the chlorpyrifos registration review or the proposed revocation.

Agencies need to "consider and respond to significant comments received during the period for public comment" on proposed rules. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015); *see also* 5 U.S.C. § 553(c) (agency must give consideration to relevant matter, including data and arguments submitted during the comment period on proposed rules). Of particular relevance to this proceeding, when resolving a petition to revoke tolerances and deciding to leave a tolerance in effect, EPA must consider "information available to the Administrator" and specifically information relevant to such statutorily mandated considerations as pre- and post-natal neurotoxicity, children's exposures, population sensitivities, and gaps in

[52] If scientific uncertainties prevent EPA from identifying an acceptable exposure level that will prevent damage to children's brains, EPA must use additional safety factors due to pre-natal and post-natal neurotoxicity from chlorpyrifos. See Earthjustice, et al., Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) at 2-11; 2016 SAP 18-19.

information. 21 U.S.C. § 346a(b)(2)(C)-(D) and § 346a(d)(4)(A); *see also* Dichlorvos (DDVP); Order Denying NRDC's Objections and Requests for Hearing, 73 Fed. Reg. 42683, 42696 (July 23, 2008) (EPA recognizes its obligation to provide a reasoned explanation for its treatment of significant comments when acting on petitions to revoke tolerances).

While EPA has apparently heeded some unspecified and vaguely referenced comments from Dow Agrosciences and others who want to retain chlorpyrifos tolerances, it is silent as to the multiple and extensive comments offering scientific reasons why the 2014 risk assessment and proposed revocation do not protect children and violate governing legal standards.

Particularly formidable are the numerous, well-supported comments from scientists, health professionals, and farmworker and health advocates making the case that EPA is failing to protect against the most sensitive health effect — harm to children's developing brains – because the 2014 risk assessment and proposed revocation use 10% cholinesterase inhibition as the regulatory endpoint.[53] If EPA had either lowered its regulatory endpoint or used the traditional and FQPA safety factors to guard against such brain impairments, it would have, as it did in 2016, found unsafe exposures in food, from drift 300 feet or more from the application site, and in drinking water nationwide. 2016 RHHRA at 23-24, 30-33.[54]

In denying the 2007 Petition, EPA did not disavow its prior findings that chlorpyrifos is unsafe. Nor could it credibly do so in light of the overwhelming scientific evidence correlating low-level chlorpyrifos exposures with damage to children's developing brains. If EPA were to modify the particular brain-protective endpoint used in the 2016 risk assessment, it would need to ensure that the endpoint selected, possibly coupled with additional safety factors, would produce a risk assessment that protects children from permanent brain damage from chlorpyrifos exposures. The only way EPA can ensure there is reasonable certainty of no harm from chlorpyrifos exposures is to account for the evidence of such harm from exposures far below the regulatory endpoint underpinning the current tolerances.

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[53] *See, e.g.*, 2015 Farmworker Comments; Comments to EPA from Environmental Health Scientists and Healthcare Professionals in support of EPA's 2016 Revised Human Health Risk Assessment and the 2015 proposed tolerance revocation for chlorpyrifos (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0587); Comments to EPA submitted on behalf of University of California, Davis scientists with the UC Davis Environmental Health Sciences Center and the UC Davis Center for Children's Environmental Health in support of EPA's 2016 Revised Human Health Risk Assessment in conjunction with the 2015 proposed rulemaking to revoke tolerances for chlorpyrifos (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0640); Comments to EPA from Environmental Health Scientists and Healthcare Professionals in support of EPA's Proposal to Revoke Chlorpyrifos Food Residue Tolerances (Jan. 5, 2016) (EPA-HQ-OPP-2015-0653-0374); Comment submitted by Harry Wang, Vice-President, Physicians for Social Responsibility/Sacramento (Apr. 30, 2015) (EPA-HQ-OPP-2008-0850-0834).

[54] *See also* Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 5, 2016) at 8-10 (If EPA had used a 1000X safety factor, it would have found risks of concern to all children from food, even without using an endpoint that reflects the harm to the developing brain, with children 1-2 years old facing the highest risks, more than 2 times EPA's level of concern.).

Public comments raised several other significant issues that EPA would need to address if it persists in leaving chlorpyrifos tolerances in place in response to the 2007 Petition.[55] First, the farmworker and health advocate comments disputed EPA's legal authority to ignore inhalation exposures from chlorpyrifos spraying, which EPA tried to justify because the labels prohibit allowing a pesticide to drift onto people. Chlorpyrifos drift poisons people every year, documenting that the label prohibition is ineffective and greater safeguards are needed to provide reasonable certainty of no harm. 2015 Farmworker Comments at 43-49.

Second, while EPA recognized in its 2011 preliminary risk assessment that chlorpyrifos has a propensity to volatilize after application and move large distances as vapor, and that buffers as large as 4000 feet may be necessary to prevent harm from exposures to chlorpyrifos vapors, it ultimately disregarded volatilization exposures based on two rat studies submitted by Dow Agrosciences that purport to show that it is impossible to inhale enough chlorpyrifos to produce an adverse effect. Public comments pointed out that the Dow studies suffer from significant flaws because they fail to address temperature and soil moisture impacts on volatilization, individual variation, a lack of controls to ensure the experiment could detect cholinesterase inhibition, and biomonitoring and incident data showing harmful exposures at distances as large as one-half mile from application sites. 2015 Farmworker Comments at 50-58.

Third, the comments submitted California incident data documenting poisonings from chlorpyrifos at far greater distances than the spray drift buffers put in place by the registrants in 2012. These real-life impacts show that reasonable certainty of harm persists. This year on Cinco de Mayo, roughly one dozen farmworkers in Kern County, California, were poisoned and a total of 50 put at risk from spray drift of what has been reported to be chlorpyrifos.[56] Local news described how "twelve people reported symptoms of vomiting [and] nausea and one person fainted." *Id.* The farmworkers were harvesting cabbage at a farm that does not use chlorpyrifos when drift from a nearby field led workers to complain of "a bad odor, nausea and vomiting."[57] Following the incident, the Kern County Department of Agriculture and Measurement Standards stated that testing was still underway, but confirmed that they are investigating a ground application of chlorpyrifos that took place one-half mile from where the poisoning occurred.

Fourth, not only did EPA continue to use poisoning as its regulatory endpoint, it used a model developed by Dow AgroSciences to try to pinpoint the exposures that will produce 10% cholinesterase inhibition in people. Public comments objected to use of the model because, in February 2011, EPA's Scientific Advisory Panel found numerous flaws in the model, using terms like "very problematic," "cursory," "overstated," "inadequate," "inaccurate," "imprecise,"

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[55] Objectors incorporate by reference all comments submitted by Objectors under docket numbers EPA-HQ-OPP-2007-1005, EPA-HQ-OPP-2008-0850, and EPA-HQ-OPP-2015-0653.

[56] Tom Philpott, *Trump's EPA Greenlights a Nasty Chemical. A Month Later, It Poisons a Bunch of Farmworkers*., Mother Jones (May 15, 2017, 6:00 AM) http://www.motherjones.com/environment/2017/05/california-farm-workers-just-got-poisoned-nasty-pesticide-greenlghted-trump.

[57] Oliver Milman, *Pesticide that Trump's EPA refused to ban blamed for sickening farm workers*, The Guardian (May 17, 2017, 7:00 AM), https://www.theguardian.com/environment/2017/may/17/pesticide-trump-ban-california-farm-workers-sick.

and "incomplete."[58] Dow made some changes in the model, but EPA did not obtain another review by its Scientific Advisory Panel.

In addition, the model is based on ethically and scientifically deficient studies. Congress has required that human testing must meet minimal ethical and scientific standards before EPA can rely on such tests. An EPA ethics advisor found that the key Dow human study fell short of meeting informed consent requirements, and EPA's Human Studies Review Board found the study scientifically deficient in two respects that have not been corrected. EPA has since strengthened its regulatory standards governing use of intentional human dosing studies, yet EPA failed to resubmit the study to the Human Studies Review Board. EPA has provided no credible basis for relying on human testing without subjecting it to such scrutiny and without confronting the earlier findings of ethical and scientific shortcomings. 2015 Farmworker Comments at 36-42.

Based on the Dow model, EPA eliminated the inter-species safety factor altogether, and it shrank the intra-species safety factor from 10X to 4X-5X for children, although it retained a 10X for women of childbearing age since the Dow model lacks data reflecting how a pregnant woman's body processes chlorpyrifos. The result — under the 2014 risk assessment —EPA will allow chlorpyrifos exposures to be an order of magnitude higher for pregnant women and even higher still for children than would be allowed if traditional safety factors had been retained. Comments argued that EPA cannot use Dow's model to eliminate or reduce the safety factors in light of the neurodevelopmental effects that occur at lower doses than those used in the model. 2015 Farmworker Comments at 28-32. If EPA had heeded these comments and had retained the traditional safety factors, it would have found in 2014 that chlorpyrifos is unsafe on food as well as in drinking water, and that children are at even greater risk from chlorpyrifos drift and workers from handling the pesticide or re-entering fields shortly after chlorpyrifos spraying.

### C. Widespread Use of Chlorpyrifos in Agriculture is Legally Irrelevant Because Congress Made Protecting Food Safety and Preventing Neurodevelopmental Harm to Children Paramount.

The Pruitt Order states:

> Although not a legal consideration, it is important to recognize that for many decades chlorpyrifos has been and remains one of the most widely used pesticides in the United States, making any decision to retain or remove this pesticide from the market an extremely significant policy choice.

82 Fed. Reg. at 16,590; *see also id.* at 16,584 ("chlorpyrifos is currently the only cost-effective choice for control of certain insect pests."). The Pruitt Order then cites the significance of the decision as a reason for further study of the risks before taking final regulatory action. *Id.*

EPA issued a press release on the Pruitt Order noting that chlorpyrifos is "one of the most widely used pesticides in the world" and quoting EPA Administrator Scott Pruitt as saying, "We need to provide regulatory certainty to the thousands of American farms that rely on

[58] Meeting minutes, report, and background material is available in Docket EPA-HQ-OPP-2010-0588 and on the SAP meetings website at: http://www.epa.gov/scipoly/sap/meetings/2011/021511meeting.html.

chlorpyrifos." The EPA press release included a statement from Sheryl Kunickis, director of the Office of Pest Management Policy at the U.S. Department of Agriculture ("USDA"), endorsing the Pruitt Order because it "frees American farmers from significant trade disruptions that could have been caused by an unnecessary, unilateral revocation of chlorpyrifos tolerances in the United States."[59] EPA released another press statement on April 5, 2017, compiling statements from USDA and various agricultural associations praising EPA's decision not to ban chlorpyrifos.[60]

As the Pruitt Order acknowledges, however, EPA must make food tolerance decisions based on safety and in particular whether EPA can find that there is a reasonable certainty of no harm from the pesticide. Congress decided long ago that the safety of our food cannot be sacrificed, and in 1996, it expanded that mandate to aggregate exposures to a pesticide in food, drinking water, and pesticide drift. EPA cannot leave tolerances in place in the absence of a finding of safety, no matter how widely used the pesticide is.[61] Indeed, widespread use of chlorpyrifos cuts the other way because its use exposes children and communities throughout the country to poisoning and brain damage risks, making the Administrator's decision to delay protections even more egregious.

D. The Deadline for Completing Registration Review for All Older Pesticides is Not A License to Maintain Tolerances for Pesticides That are Unsafe

As a final reason for denying the 2007 Petition and leaving chlorpyrifos tolerances in place, EPA claims the right to re-order the priorities that had been set by previous administrations. It asserts that it can put off deciding whether to revoke chlorpyrifos tolerances for years as long as it does so before October 1, 2022, the deadline for completing registration review of all older pesticides. 82 Fed. Reg. 16,581, 16,590 (April 5, 2017); *see* 7 U.S.C. § 136a (g)(1)(A)(iii)(I) (registration review deadline). This position is indefensible because it ignores other legal mandates and the scientific evidence that precludes the safety finding that is necessary to leave chlorpyrifos tolerances in place.

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[59] Press Release, U.S. EPA, EPA Administrator Pruitt Denies Petition to Ban Widely Used Pesticide (Mar. 29, 2017), https://www.epa.gov/newsreleases/epa-administrator-pruitt-denies-petition-ban-widely-used-pesticide-0.

[60] Press Release, U.S. EPA, Agriculture Community Reacts to Recent EPA Action (Apr. 5, 2017), https://www.epa.gov/newsreleases/agriculture-community-reacts-recent-epa-action.

[61] Chlorpyrifos usage has declined over time, as many farmers have shifted to less toxic alternatives, even before EPA's proposal to revoke chlorpyrifos tolerances. Annual agricultural pesticide use data compiled by the U.S. Geological Survey's Pesticide National Synthesis Project show that, since the mid-1990s, chlorpyrifos use has declined. https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php year=2014&map=CHLORPYRIFOS&hilo=L&disp=Chlorpyrifos. Additionally, in California, the combined use of chlorpyrifos in alfalfa, almonds, citrus, and cotton decreased from 2006 -2012. While overall use increased in 2013 and 2014, it remained below the amount used in 2006. "Identifying and Managing Critical Uses of Chlorpyrifos Against Key Pests of Alfalfa, Almonds, Citrus and Cotton" (UC IPM report for CA DPR), August 31, 2016 at 3.

Under the FFDCA, any person may file a petition to revoke tolerances. 21 U.S.C. § 346a(d)(1). The Administrator must give the petition due consideration and issue either a proposed or final regulation to revoke the tolerances or an order denying the petition. *Id.* § 346a(d)(4)(A). While the FFDCA does not establish a specific deadline for acting on petitions to revoke tolerances, the Administrative Procedure Act requires that federal agencies respond to petitions "within a reasonable time." 5 U.S.C. § 555(b). In 2015, the Ninth Circuit held that EPA's delay in responding to the 2007 Petition was unreasonable and "egregious" and set a timeline for EPA to respond. *In re Pesticide Action Network North America v. EPA*, 798 F.3d 809, 811 (9th Cir. 2015). In 2016, the court reiterated its concerns over any further delay, stating that any "claim of premature rulemaking has come and gone." *In re PANNA*, No. 14-72794, Order (9th Cir. Aug. 12, 2016).

The fact that Congress established an October 1, 2022, deadline for EPA to complete registration review of all older pesticides is no license for EPA to continue to exacerbate its unreasonable delay in acting on the 2007 Petition seeking revocation of chlorpyrifos tolerances. First, the registration review provision states that: "Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide . . ." 7 U.S.C. § 136a(g)(1)(C). This clause prohibits EPA from relying on the registration review deadline to forestall other legally required or scientifically compelled regulatory action.

Second, it is FIFRA, not the FFDCA, that establishes the registration review process. While registration review will include an assessment of food and drinking water risks and determine whether food tolerances may be retained or must be revoked, registration review is far broader in scope than the issues arising under the FFDCA. It will examine all uses of a pesticide, not only food uses, and risks to wildlife, waterbodies, and workers in addition to food and drinking water. In addition, FFDCA tolerance determinations must be made solely on the basis of safety, while nonfood use decisions under FIFRA are based on a balancing of risks and benefits. *Compare* 21 U.S.C. § 346a(b)(2)(A)(i) & (ii) (FFDCA standard and determination of safety), *with* 7 U.S.C. § 136(bb) (FIFRA definition of "unreasonable adverse effects on the environment"). Even where EPA accelerates food safety determinations, as it had done for chlorpyrifos, other FIFRA assessments and decisions lie ahead and remain subject to the 2022 registration review deadline.

EPA's review of chlorpyrifos has proceeded to a point of no return. The agency developed methods for addressing spray drift, volatilization, and epidemiology studies, and released human health risk assessments that document unsafe exposures from chlorpyrifos. EPA made findings that chlorpyrifos is unsafe in 2014 directed at drinking water contamination, *see, e.g.*, 80 Fed. Reg. 69,080, and expanded those findings in November 2016 to every way people are exposed to chlorpyrifos. 81 Fed. Reg. at 81,050. The law is clear. EPA can leave food tolerances in place only if it can find the pesticide safe. Because EPA has found chlorpyrifos to be unsafe, it lacks the authority to retain the food tolerances. It cannot lawfully issue an order denying the 2007 Petition, but instead must comply with the FFDCA mandate to revoke tolerances for this unsafe pesticide.

In claiming the authority to postpone revoking chlorpyrifos tolerances despite its own scientific findings, EPA cites the prerogative of a new presidential administration to make policy choices that differ from its predecessor, citing *Fed. Commc'n Comm'n v. Fox Television*

*Stations*, 556 U.S. 502 (2009). 82 Fed. Reg. at 16,589. *Fox Television*, however, requires agencies to provide a reasoned explanation that comports with *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 43 (1983), and to address prior factual findings and circumstances that underlay the earlier agency decision. 556 U.S. at 515-16. EPA provided no such explanation, and it has not disavowed its previous findings that chlorpyrifos is unsafe. Nor could it given the extensive scientific record documenting the damage chlorpyrifos causes to children's brains at low-level exposures. Whatever leeway a new administration has to make its own policy choices does not extend to factual determinations, like EPA's findings that chlorpyrifos is unsafe. Nor does that latitude allow the new administration to break the law by leaving tolerances in place in the face of findings of such serious harm to children.

## CONCLUSION

For these reasons, EPA must reverse the Pruitt Order and revoke all chlorpyrifos tolerances. This misguided Order and the delay it has spurred threaten to expose countless children and communities to chlorpyrifos well into the future. People will needlessly suffer from poisonings from chlorpyrifos drift. Parents will watch their children struggle with attention disorders and impaired brain functioning that hinders their ability to learn and play, and the children will experience lifelong deficits that make it harder for them to achieve their full potential and dreams. Prolonging revocation of chlorpyrifos tolerances, as required by the law and science, is not only unlawful, but also callous and heartless. EPA should rule on these objections within 60 days and expedite revocation of all chlorpyrifos tolerance.

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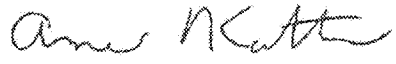

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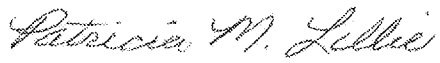

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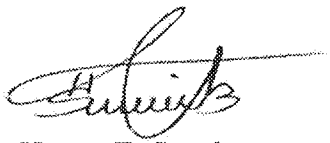

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